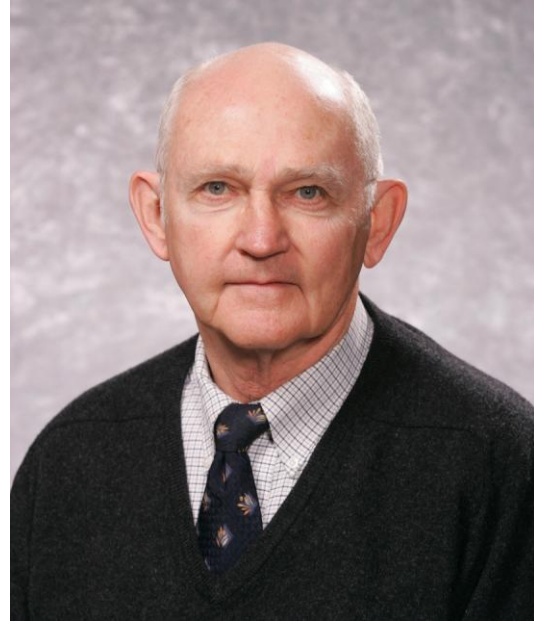


The Current International Quality Standard, ISO 9001:2008

What your company needs to know

By [Merle Pochop](#)

Changes in ISO standards are routine. But they still manage to cause a fair amount of trepidation. For example, anyone who experienced the 1994 version of the ISO 9000 Quality Management Standard might have worried about the shift to ISO 9001:2000. The 1994 standard focused largely on traditional manufacturing activities and concentrated a good deal of its regulation on production activities. Specifically, the standards seemed geared to companies whose processes involved actions applied to discrete objects, while other companies, particularly service organizations and those involved in continuous flow processes,



found themselves "going through the paces," with little tangible benefit other than the reputation gained by certification. For many people charged with applying the standard, it seemed like a lot of busy work.

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Happily, when the draft version of ISO 9001:2000 became available, it signaled major changes to the application of the quality management system. The technical committee listened to testimony from users and consequently took a back-to-basics approach. And while major components of the 1994 version were still recognizable, the 2000 standard placed greater responsibility on management involvement. At the same time, operators became more responsible for their own work, the customer-centric focus was more clearly defined, and the principle that an ISO-certified company must show continual improvement became firmly established.

These changes were welcome. But one important issue remained: how to effectively determine whether an ISO 9001:2000 certified company was implementing the system in such a way that improvement was measurable. In many cases, people using the system felt that it was not completely beneficial. Quality improvements were taking place, but those improvements appeared random, and if directed, seemed to focus on traditional areas such as shop or service operations.

ISO 9001 registrars recognized this difficulty. They believed the issue could be dealt with by revising the audit practices used for reviewing already certified companies. Registrar auditing, as well as the required internal auditing, had concentrated on determining whether the quality management system was in place, and whether it was in use. Looking forward,

registrars determined that it was important to add one more requirement: whether the QMS was effective. The requirement was clear, but how to accomplish this?

Step by step

The solution devised by registrar auditing teams was to adopt a practice known as process auditing. For those who don't know, process auditing is a standardized approach to reviewing an activity by dividing it into basic components of:

1. Inputs
2. Process steps
3. Outputs

Every activity in an ISO-certified company can be analyzed using this methodology. In order to better evaluate how well the company had implemented its QMS, registrars also added standard questions to the audit, asking for knowledge and demonstrations of process/performance improvement goals for each area of the company. With this approach, companies became more aware that process improvement wasn't simply a shop-operations practice; it was everyone's responsibility. So for the first time, a company's support activities such as sales, purchasing, engineering and personnel were required to show how they were working to improve customer satisfaction as well.

ISO 9001:2008 was approved for implementation at the beginning of 2009. For the casual reader, the changes might seem hard to discern. And for the most part, the changes are only intended to clarify and improve language. However, there is an important change in the wording of the introduction that encourages organizations to consider and use the process approach as a way to improve customer satisfaction and increase value.

From a practical standpoint, what this means is that companies currently using the process approach to auditing should talk to their registrar before making any changes to their QMS. One additional activity that needs to be carried out now that the new standards have been issued is to review all documentation for correct terminology. Failure to upgrade the term ISO 9001:2000 to ISO 9001:2008 might seem like a small thing. But it can become a sticking point if registrars spot it too often.

Merle Pochop, project manager at the Center for Industrial Research and Service, has personally guided more than 50 companies through the ISO certification process. While collectively, CIRAS specialists have helped more than 300 Iowa firms become ISO certified. To learn how ISO certification could benefit your company, For more information, please contact Merle Pochop at 712-274-0048; pochop@iastate.edu. Or, contact a CIRAS account manager; www.ciras.iastate.edu, 515-294-3420.

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